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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,875

03/08/2004

Keith G. Lurie

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20350

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04/21/2006

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/796,875		LURIE ET AL.	
	Examiner		Art Unit	
	Nihir Patel		3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02.10.2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03.14.2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on February 10, 2006 have been fully considered but they are not persuasive. The applicant argues that none of the claims of the cited applications or patents include the limitation relating to the timing of the extraction of respiratory gases being at least 0.1 to about 0.5 of the positive pressure breath to maintain the negative pressure in the thorax. Claims of patent 6,938,618 and application 10/660,462 do recite the limitations.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 contains subject matter "at least about 0.1 to about 0.5 of the inspiration of the respiratory gases delivered by the means to deliver a positive pressure breath to thereby maintain the negative intrathoracic pressure" which was not described in the specification.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims **1, 3 and 4** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **1** of **U.S. Patent No. 6,938,618**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between **claim 1** of the current application and claim 1 of patent ‘618 lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 of patent ‘618 is in effect a “species” of the “generic” invention of claim 1 of the current application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 of current application is anticipated by claim 1 of patent ‘618, it is not patentably distinct from claim 1 of patent ‘618. **With respect to claim 3 of the current application**, the limitations can be found in

claim 2 of patent '618. **With respect to claim 4 of the current application**, the limitations can be found in claim 3 of patent '618.

5. Claims **1, 3 and 7 through 16** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/660,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between **claims 1 and 3** of the current application and **claims 1 and 10** of copending application 10/660,462 lies in the fact that the copending application 10/660,462 includes many more elements and is thus much more specific. Thus claim 1 of copending application 10/660,462 is in effect a "species" of the "generic" claim 1 of the current application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 patentably distinct from claim 1 of the copending application. **With respect to claim 7 of the current application**, the limitations can be found in claim 3 of the copending application 10/660,462. **With respect to claim 8 of the current application**, the limitations can be found in claim 4 of the copending application 10/660,462. **With respect to claim 9 of the current application**, the limitations can be found in claim 5 of the copending application 10/660,462. **With respect to claim 10 of the current application**, the limitations can be found in claim 6 of the copending application 10/660,462. **With respect to claim 11 of the current application**, the limitations can be found in claim 7 of the copending application 10/660,462. **With respect to claim 12 of the current application**, the limitations can be found in claim 8 of the copending application 10/660,462. **With respect to claim 13 of the current application**, the limitations can be found in claim 9 of the current application 10/660,462. **With respect to claim 14 of the current application**, the limitations

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can be found in claim 11 of the copending application 10/660,462. **With respect to claim 15 of the current application**, the limitations can be found in claim 12 of the copending application 10/660,462. **With respect to claim 16 of the current application**, the limitations can be found in claim 13 of the copending application 10/660,462.

6. Claims **17 and 20** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/660,462 in view of Idris (US 5,685,298). **Claim 17 of the current application** limitations can be found in claim 1 of the copending application 10/660,462 except for claim 17, recites a means to interface with the patient's airway; Idris discloses an apparatus that does provide a means to interface with the patient's airway. Therefore it would have been obvious to modify the copending application 10/660,462 by providing a means to interface with the patient's airway in order to prevent leakage and obtain maximum treatment. **With respect to claim 20 of the current application**, the limitations can be found in claim 9 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims **1-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Biondi et al. (US 5,377,671). Biondi discloses the applicant's invention as claimed with the exception of disclosing the ranges of different system parameters, such as breath delivery time and rate, vacuum pressure and intrathoracic pressure levels. At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to optimize the most effective variables of this method to achieve optimal results, such as reducing intracranial pressures. Therefore it would have been obvious to modify the method of Biondi by utilizing the specific ranges of breath delivery time and rate, vacuum pressure and intrathoracic pressure levels because it is well known in the art to provide different parameters of breath delivery time. Also the system parameters would be varied on patient criteria such as age of the user, disease, process, disease to be treated in order to provide appropriate ventilation which would be obvious to one of ordinary skill in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel
Art Unit 3743



Henry Bennett
Supervisory Patent Examiner
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